

IN THE CLAIMS:

1. (currently amended) A stable fixed dose oral pharmaceutical formulation selected from the group consisting of a powder, a tablet, and a capsule, wherein said powder, tablet, or capsule comprises ~~comprising at least one~~ an anti-infective agent selected from the group consisting of betalactams, fluoroquinolones, macrolides and betalactamase inhibitors ~~as a first active ingredient~~ and ~~at least one~~ a microorganism susceptible to said anti-infective agent, ~~but wherein the microorganism is~~ useful in preventing or minimizing adverse effects of said anti-infective agent ~~as a second active ingredient~~, at least one of the anti-infective agent and the microorganism ~~first and second active ingredients~~ being coated to provide a protective barrier around it, ~~said at least one of the first and second active ingredients, the first and second active ingredients being contained in a single pharmaceutical formulation selected from the group consisting of a powder, a tablet, and a capsule, wherein said powder, tablet, or capsule contains both said anti-infective agent and said microorganism~~, the protective barrier protecting the susceptible microorganism from the effect of the anti-infective agent to maintain the susceptible microorganism in a viable form for a period of at least three months.

2. (original) The formulation of claim 1 wherein said anti-infective agent is selected from the group consisting of Ampicillin, Amoxycillin, Cloxacillin, Clavulanic acid, Sultamicin, Cefuroxime axetil, Cefadroxyl, Cephalexin, Cefixime, Erythromycin, Ciprofloxacin, and combinations thereof.

3. (currently amended) The formulation of claim ~~[[2]]~~ 1 wherein said microorganism is selected from the group consisting of Lactobacillus acidophilus, Lactobacillus spores, Lactobacillus lactis, Streptococcus thermophilus, Streptococcus lactis, Saccromyces cerevisea, Lactobacilli GG, and combinations thereof.

4. (original) The formulation of claim 1 wherein the ratio of anti-infective agent to microorganism is in the range of 2:1 to 25:1.

5. (original) The formulation of claim 4 wherein the ratio of anti-infective agent to microorganism is about 5:1.

6. (original) The formulation of claim 1 wherein at least one of the anti-infective agent and the microorganism is coated with a physiologically acceptable excipient to provide granules of the anti-infective agent or the microorganism.

7. (original) The formulation of claim 6 wherein both the anti-infective agent and the microorganism are coated with an excipient to provide granules of the anti-infective agent and granules of the microorganism.

8. (original) The formulation of claim 7 wherein the anti-infective agent granules and the microorganism granules are formed into a layered tablet such that one layer contains the anti-infective agent and the other layer contains the microorganism.

9. (original) The formulation of claim 6 wherein the excipient is ethyl cellulose.

10. (original) The formulation of claim 6 wherein the excipient is a mixture of microcrystalline cellulose and starch.

11. (original) The formulation of claim 6 wherein the excipient is a mixture of magnesium stearate, polyplasdone XL and sodium chloride.

12. (currently amended) The formulation of claim 1 wherein one of the ~~first and second active ingredients~~ anti-infective agent and the microorganism is formed into a coated tablet, and wherein said coated tablet is contained in a capsule containing the other ~~active ingredient~~ of the anti-infective agent and the microorganism.

13. (original) The formulation of claim 12 wherein said tablet contains said microorganism admixed with physiologically acceptable excipients.

14. (original) The formulation of claim 1 wherein the coating comprises a compound selected from the group consisting of cellulose acetate phthalate; poly(butylmethacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate); poly(ethyl acrylate, methyl methacrylate); poly(methacrylic acid, methyl methacrylate); poly(methacrylic acid, ethyl acrylate); poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride); hydrogenated Castor oil; Cetyl alcohol; diethyl phthalate; ethyl cellulose; hydroxypropyl cellulose; hydroxypropyl methylcellulose phthalate; and zein.

15. (currently amended) A stable fixed dose oral pharmaceutical tablet comprising at least one an anti-infective agent as a first active ingredient selected from the group consisting of betalactams, fluoroquinolones, macrolides and betalactamase inhibitors and ~~at least one a~~ microorganism susceptible to said anti-infective agent as a second active ingredient, the anti-infective agent first active ingredient and an excipient forming a first discrete region of the tablet, and the microorganism second active ingredient and an excipient forming a second discrete region of the tablet, the first and second regions being such that the first and second active ingredients are physically separated in the tablet by a coating, the coating protecting the microorganism from the anti-infective agent, wherein the first region is substantially free of the microorganism second active ingredient and the second region is substantially free of the anti-infective agent first ingredient, the tablet maintaining the susceptible microorganism in a viable form for a period of at least three months. [[.]]

16. (canceled)

17. (canceled)

18. (currently amended) The tablet of claim 15 wherein at least one of the anti-infective agent and the microorganism first active ingredient and the second active ingredient is coated with an excipient to provide granules ~~of at least one of the first and second active~~

~~ingredients, the granules of said at least one of the first and second active ingredients being~~
which are compressed separately to form a tablet part.

19. (canceled)

20. (canceled)

21. (canceled)

22. (currently amended) The ~~tablet~~ formulation of claim ~~[[15]]~~ 39 wherein said anti-infective agent is selected from the group consisting of betalactams, fluoroquinolones, macrolides, and beta lactamase inhibitors.

23. (previously presented) The formulation of claim 1 wherein said anti-infective agent causes diarrhoea, and wherein the microorganism prevents or minimizes diarrhoea induced by the anti-infective agent.

24. (canceled)

25. (new) A stable fixed dose oral pharmaceutical formulation selected from the group consisting of a powder, a tablet, and a capsule, wherein said powder, tablet, or capsule comprises an anti-infective agent and a microorganism susceptible to said anti-infective agent, wherein the microorganism is useful in preventing or minimizing adverse effects of said anti-infective agent, at least one of the anti-infective agent and the microorganism being coated to provide a protective barrier around it, the protective barrier protecting the susceptible microorganism from the effect of the anti-infective agent to maintain the susceptible microorganism in a viable form for a period of at least three months,

wherein said anti-infective agent is selected from the group consisting of Ampicillin, Amoxycillin, Cloxacillin, Clavulanic acid, Sultamicin, Cefuroxime axetil, Cefadroxyl, Cephalexin, Cefixime, Erythromycin, Ciprofloxacin, and combinations thereof, and

wherein said microorganism is selected from the group consisting of *Lactobacillus acidophilus*, *Lactobacillus* spores, *Lactobacillus lactis*, *Streptococcus thermophilus*, *Streptococcus lactis*, *Saccromyces cerevisea*, *Lactobacilli* GG, and combinations thereof.

26. (new) The formulation of claim 25 wherein the ratio of anti-infective agent to microorganism is in the range of 2:1 to 25:1.

27. (new) The formulation of claim 25 wherein at least one of the anti-infective agent and the microorganism is coated with a physiologically acceptable excipient to provide granules of the anti-infective agent or the microorganism.

28. (new) The formulation of claim 27 wherein both the anti-infective agent and the microorganism are coated with an excipient to provide granules of the anti-infective agent and granules of the microorganism.

29. (new) The formulation of claim 28 wherein the anti-infective agent granules and the microorganism granules are formed into a layered tablet such that one layer contains the anti-infective agent and the other layer contains the microorganism.

30. (new) The formulation of claim 27 wherein the excipient is ethyl cellulose.

31. (new) The formulation of claim 27 wherein the excipient is a mixture of microcrystalline cellulose and starch.

32. (new) The formulation of claim 27 wherein the excipient is a mixture of magnesium stearate, polyplasdone XL and sodium chloride.

33. (new) The formulation of claim 22 wherein one of the first and second active ingredients is formed into a coated tablet, and wherein said coated tablet is contained in a capsule containing the other active ingredient.

34. (new) The formulation of claim 33 wherein said tablet contains said microorganism admixed with physiologically acceptable excipients.

35. (new) The formulation of claim 22 wherein the coating comprises a compound selected from the group consisting of cellulose acetate phthalate; poly(butylmethacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate); poly(ethyl acrylate, methyl methacrylate); poly(methacrylic acid, methyl methacrylate); poly(methacrylic acid, ethyl acrylate); poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride); hydrogenated Castor oil; Cetyl alcohol; diethyl phthalate; ethyl cellulose; hydroxypropyl cellulose; hydroxypropyl methylcellulose phthalate; and zein.

36. (new) A stable fixed dose oral pharmaceutical tablet comprising an anti-infective agent and a microorganism susceptible to said anti-infective agent, the anti-infective agent and an excipient forming a first discrete region of the tablet, and the microorganism and an excipient forming a second discrete region of the tablet, the first and second regions being physically separated in the tablet by a coating, the coating protecting the microorganism from the anti-infective agent, wherein the first region is substantially free of the microorganism and the second region is substantially free of the anti-infective agent, the tablet maintaining the susceptible microorganism in a viable form for a period of at least three months,

wherein said anti-infective agent is selected from the group consisting of Ampicillin, Amoxycillin, Cloxacillin, Clavulanic acid, Sultamicin, Cefuroxime axetil, Cefadroxyl, Cephalixin, Cefixime, Erythromycin, Ciprofloxacin, and combinations thereof, and

wherein said microorganism is selected from the group consisting of Lactobacillus acidophilus, Lactobacillus spores, Lactobacillus lactis, Streptococcus thermophilus, Streptococcus lactis, Saccromyces cerevisea, Lactobacilli GG, and combinations thereof.

37. (new) The tablet of claim 36 wherein the anti-infective agent and the microorganism are coated with an excipient to provide granules of the anti-infective agent and the microorganism, the granules being compressed separately to form a tablet part.

38. (new) A stable, dry, fixed dose oral pharmaceutical formulation comprising (a) an anti-infective agent capable of causing adverse effects caused by destruction of commensals, (b) a microorganism useful in preventing or minimizing the adverse effects of said anti-infective agent, and (c) a protective barrier between the anti-infective agent and the microorganism, wherein the anti-infective agent would destroy the viability of the microorganism in the dry formulation in less than three months in the absence of the protective barrier, and wherein the protective barrier protects the susceptible microorganism from the effect of the anti-infective agent to maintain the susceptible microorganism in a viable form for a period of at least three months.

39. (new) The formulation of claim 38 wherein said anti-infective agent causes diarrhoea, and wherein the microorganism prevents or minimizes diarrhoea induced by the anti-infective agent.

40. (new) The formulation of claim 38 wherein said anti-infective agent is selected from the group consisting of Ampicillin, Amoxycillin, Cloxacillin, Clavulanic acid, Sultamicin, Cefuroxime axetil, Cefadroxyl, Cephalexin, Cefixime, Erythromycin, Ciprofloxacin, and combinations thereof, and

wherein said microorganism is selected from the group consisting of Lactobacillus acidophilus, Lactobacillus spores, Lactobacillus lactis, Streptococcus thermophilus, Streptococcus lactis, Saccromyces cerevisea, Lactobacilli GG, and combinations thereof.